UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 Honorable Robert B. Kugler, District Court Judge
This Document Relates to All Actions	Oral Argument Requested

DEFENDANTS' REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF JOINT MOTION TO EXCLUDE THE OPINIONS OF JOHN QUICK

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INTRODUCTION

Plaintiffs' Response in Opposition to Defendants' Motion to Exclude the Opinions of John Quick ("Plaintiffs' Response"), (ECF No. 2085), seeks to sidestep the fundamental problem with Mr. Quick's opinions—i.e., he has provided impermissible legal and regulatory conclusions, particularly with respect to cGMP. As Defendants explained in their motion, Mr. Quick's fundamental opinion that any violation of cGMPs at a facility renders all products manufactured at that facility "adulterated," and by extension, that all of the Defendants' valsartan-containing drugs ("VCDs") should be considered "adulterated" is inadmissible because: (1) Mr. Quick's opinions seek to usurp the role of the FDA and the Court; and (2) Mr. Quick misinterprets FDA regulations in a manner that would have staggering consequences. (*See generally* Defendants' Memorandum of Law in Support of Defendants' Joint Motion to Exclude the Opinions of John Quick ("Defendants' Motion"), (ECF No. 2035-1).)

Plaintiffs also argue that Mr. Quick's impermissible regulatory and legal conclusions are "facts" rather than conclusions. But the opinion that a product was adulterated under the FD&C Act is the very definition of a regulatory determination reserved for the FDA. And if Mr. Quick were simply stating "facts," his proposed expert testimony would serve no purpose and would not assist the factfinder.

Nor should the Court defer consideration of Defendants' motion as Plaintiffs suggest in their brief. Plaintiffs designated Mr. Quick as a class certification expert, and they must demonstrate that his opinions are admissible. Moreover, the fact that Mr. Quick's opinions are being offered to support class certification, rather than to support liability on the merits, is immaterial for purposes of the standards applicable to determining the admissibility of an expert's opinions under the Federal Rules of Evidence.

Plaintiffs attempt to back away from Mr. Quick's opinion in their Response, but a party cannot survive a Rule 702 motion by pretending that its expert's opinions are something other than what he testified to. And Mr. Quick unabashedly repeated his adulteration opinion multiple times in his Declaration and at his deposition—going so far as to acknowledge that this opinion meant the facilities he personally oversaw during his time as the Vice President of Quality and Regulatory Matters at Baxter Pharmaceuticals would have continually manufactured and sold adulterated products.

For these reasons, discussed in more detail below, and the reasons set forth in Defendants' Motion, Mr. Quick's class certification opinions should be excluded.

ARGUMENT

I. MR. QUICK'S OPINIONS CONSIST ALMOST ENTIRELY OF IMPERMISSIBLE REGULATORY AND LEGAL CONCLUSIONS.

All of Mr. Quick's class-certification opinions are based on one underlying premise, which Mr. Quick set forth in his expert Declaration and repeated numerous times at his deposition: that Defendants' alleged non-compliance with cGMPs at the relevant manufacturing facilities rendered ***all*** of Defendants' respective VCDs similarly "adulterated" under the FD&C Act. (Quick Rep. ¶¶ 26, 28-29, 32; *see, e.g.*, Quick Dep., Vol. I, 91:16-20, 95:7-10, 96:10-15, 101:12-17, 104;18-105:2, 105:25-106:6). As Defendants explained in their opening brief, this is an impermissible legal conclusion regarding a matter that is solely within the province of the FDA (i.e., whether product was "adulterated"), and the relevant caselaw overwhelmingly demonstrates that experts may not offer such testimony. Plaintiffs' arguments in response lack merit.

First, Plaintiffs limit their discussion of the long line of authorities prohibiting experts from offering legal conclusions that a product was misbranded or adulterated to a single footnote in which Plaintiffs assert that the expert opinions excluded in Defendants' cases were offered at the merits stage, rather than at class certification. (Plaintiffs' Response at 8 n.4). This is a distinction without a difference, because none of the relevant cases tie or limit their holdings to merits-based expert reports. *See, e.g.*, *In re Tylenol (Acetaminophen) Mktg., Sales Practices, & Prods. Liab.*

Litig., MDL No. 2436; Case No. 2:12-cv-07263, 2016 U.S. Dist. LEXIS 98858, at *8–9 (E.D. Pa. July 27, 2016); *Tsao v. Ferring Pharms., Inc.*, No. 4:16-cv-01724, 2018 WL 3649714, at *11 (S.D. Tex. Apr. 19, 2018); *Stanley v. Novartis Pharms. Corp.*, No. 11-03191, 2014 U.S. Dist. LEXIS 198861, at *10 (C.D. Cal. May 6, 2014); *In re: Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 557 (S.D.N.Y. 2004). Further, Third Circuit law is clear that the Rule 702 standard for evaluating expert opinions applies equally at the class-certification stage. *See In re Blood Reagents Antitrust Litig.*, 783 F.3d 183, 187 (3d Cir. 2015) (stating that when experts are "critical to class certification" their testimony is subject to "rigorous analysis" under "the standard set out in *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993)").

Plaintiffs also assert in the same footnote that *Robinson v. Ethicon*, No. 20-03760, 2022 WL 614919, at *5-6 (S.D. Tex. Mar. 2, 2022), is inapposite because the FDA had never issued any findings of adulteration as to the products at issue there. (Plaintiffs' Response at 8 n.4). But to the extent FDA found any VCD at issue in this case to be adulterated, those determinations were made only as to certain Manufacturer Defendants, did not apply retroactively, and were made only ***after all relevant VCDs had been voluntarily recalled from the United States market.*** Mr. Quick has not identified any Warning Letter or other FDA determination of "adulteration" or "misbranding" dated any earlier than November 29, 2018.

Accordingly, as discussed more fully in section II below, if Mr. Quick is merely reciting "facts" regarding the FDA's adulteration determinations, as Plaintiffs claim, he cannot testify that any VCD was adulterated prior to this date.

Second, Plaintiffs attempt to recharacterize Mr. Quick's opinion as simply reciting "facts" surrounding cGMP issues at each of the Defendants' facilities. (Plaintiffs' Response at 2-3, 6-7.) In addition, Plaintiffs seek to reframe Mr. Quick's opinion as limited to "serious, systemwide" cGMP violations. (Plaintiffs' Response at 9 n.5 "FDA policy is that serious, systemwide cGMP violations render all product from a certain facility adulterated.") But Plaintiffs cannot rewrite Mr. Quick's opinions in an effort to survive *Daubert* scrutiny. *See Tamraz v. Lincoln Elec. Co*., 620 F.3d 665, 672-73 (6th Cir. 2010) (rejecting counsel's effort to redefine the expert's opinion through briefing because the expert's "opinion cannot escape its own logic"). Mr. Quick could not have been clearer that it is his opinion that ***any*** cGMP violation identified at a facility renders ***all*** product manufactured at that facility adulterated:

> "If the finished drug facility or API manufacturing facility does not have in place, "systems that ensure proper design, monitoring, and control of manufacturing processes and facilities," the facility is not compliant with CGMP and thus **all products in the facility would be considered to be adulterated**." (Quick Rep. ¶ 26 (emphasis added)).

And he maintained this position throughout his deposition:

> "So a product could be contaminated, that would be adulteration. Or the product could be fine but if the firm failed to adhere to current

> good manufacturing practices, the products that they are making, by definition, are adulterated." (Quick Dep., Vol. I, 91:16-20).
>
> . . . .
>
> "As I previously stated, a product can be considered to be adulterated if the CGMPs were not followed in the manufacturing of the product, even if there is nothing wrong with the product." (Quick Dep., Vol. I, 95:7-10).
>
> . . . .
>
> "So as I've indicated, the FDA states that. They also -- in almost virtually every warning letter that's issued to a firm, they will say in the warning letter that the product is considered to be adulterated because CMG -- CM -- they were in violation of CGMPs." (Quick Dep., Vol. I, 96:10-15).
>
> . . . .
>
> "Q. But you say in Paragraph 32 of your report that: FDA's official position regarding CGMPs is that if a company is not complying with CGMP regulations, ***any drug it makes*** is considered adulterated under the law. A. Right." (Quick Dep., Vol. I, 101:12-17 (emphasis added)).

Mr. Quick also ***repeatedly*** declined to place any limitation on the type of cGMP issue that would cause a product to be deemed "adulterated," emphasizing that, in his opinion, the FDA does not draw any such distinction and refusing to take into account any variations or differences in the issues present at the various manufacturing facilities. According to Mr. Quick:

> "If a company is not complying with CGMP regulations, any drug it makes is considered adulterated under the law. That's what the FDA states. That's not what John Quick states. That's what the FDA states. **Q. And, again, those would have to be significant CGMP**

> **violations, significant enough to rise to that level. Correct? A. It doesn't say that. It doesn't say that here.**" (Quick Dep., Vol. I, 104:18-105:2 (emphasis added)).
>
> . . . .
>
> "Q. To determine if a product is adulterated due to CGMP violations, you would need to look at the specific violations. Correct? A. Well, again, I'll go back to what it says here. It doesn't say that, okay, in terms of that. **So it doesn't say whether it's a minor thing or major. It doesn't say that here.** Okay?" (Quick Dep., Vol. I, 105:25-106:6 (emphasis added)).

Plaintiffs' Response cites to the one line in Mr. Quick's deposition in which he acknowledged that issues like "somebody not wearing a hairnet" would, in his estimation, not amount to a cGMP violation. (Quick Dep., Vol. I, 169:4-8; Plaintiffs' Response at 10). But this statement does not contradict Mr. Quick's opinion that any cGMP violation renders all product adulterated, as he even clarified within his answer that he is talking about "GMP situations, ***not like somebody not wearing a hairnet***." (Quick Dep., Vol. I, 169:4-5 (emphasis added)).

Mr. Quick was so steadfast in his core opinion that any cGMP violation renders a product adulterated that he was forced to acknowledge that all the products manufactured at the facility he, himself, oversaw as VP of Quality for Baxter Pharmaceuticals were "adulterated" under his logic:

> "Q. Does the [Warning Letter to Baxter Pharmaceuticals] say anything about any and every product that Baxter made at the same time as -- as the observation that the investigators made were adulterated? MR. DAVIS: Objection.

A. It does. First paragraph.

Q. Did you consider, at the time that you received this letter, that each and every product that was made at that facility during the time that these observations were in effect, were adulterated?

A. We assumed that this applied to all the products that were made at the facility, yes, we did."

(Quick Dep., Vol. I, 150:13-25). Yet, as Mr. Quick admitted, Baxter Pharmaceuticals took no action to address the fact that his company was manufacturing and releasing adulterated drug product to patients (nor did Mr. Quick appear to think any action was warranted):

"Q. Did the facility go on to, for example, recall all of the product that it had on the market at the time that had been manufactured at that facility?

A. Well, there's no recall. But to answer your question, we did consider all the products to be adulterated.

Q. Did it put a distribution hold on all product manufactured at the facility?

A. No, we did not.

. . . .

Q. So, again, my question was, you didn't initiate a recall, and you didn't initiate a distribution hold, yet you considered all of the product manufactured at that facility to be adulterated?

A. Under the context of this, yes."

(Quick Dep., Vol. I, 151:1-23).

Plaintiffs' assertion in their briefing that Mr. Quick does not seek to offer the legal conclusion that all VCDs are adulterated based on cGMP violations is similarly belied by other admissions in the record. For example, Mr. Quick disregarded the need for close examination of the cGMP issues at any individual facility and was willing to apply the blanket "adulteration" determination to any product manufactured at any time at a facility where there were at least some identified cGMP issues apparent from Mr. Quick's admittedly cursory review of the documents. He also did not take into account the severity or significance of the violations, and did not explain how these issues applied retroactively or prospectively for purposes of the adulteration question (although the only logical reading of his Declaration and deposition testimony is that they apply both retroactively and prospectively, with no endpoint in either direction). In so doing, Mr. Quick purported to step into the shoes of the FDA and take it upon himself to opine that all VCDs manufactured by all Defendants during the entire relevant time period were adulterated because, "[i]f a company is not complying with CGMP regulations, any drug it makes is considered adulterated under the law. That's what the FDA states. That's not what John Quick states. That's what the FDA states." (Quick Dep., Vol. I, 104:18-22).

But Mr. Quick's improper legal conclusion is directly contradicted by the FDA's actual regulatory actions taken in response to discovery of the nitrosamine

impurities. FDA issued warning letters in late 2018 and 2019 to certain API manufacturers, all of whom had already recalled their VCDs from the market. (*See, e.g.*, ECF No. 2085-3). The FDA made no declaration that this determination applied retrospectively—specifically using the words "*are* adulterated." (*Id.* (emphasis added)). Furthermore, not all of the manufacturers in this litigation have been the subject of warning letters or any adulteration determination whatsoever by the FDA.

Mr. Quick's opinions go much further than the FDA, declaring all VCDs to be "adulterated"—regardless of when or if a given manufacturer's product was found to the "adulterated" by the FDA under the FD&C Act. Plaintiffs could not be more wrong in claiming that Defendants do not contest that cGMP issues affect all products similarly—the primary basis for Defendants' challenge is that Mr. Quick failed to consider *specific* cGMP issues or to assess their severity or impact on the VCDs at issue, leaping instead to the conclusion that regardless of any differences (which he did not assess), the products would similarly meet the FDA's regulatory definition of "adulterated" product. (*See* Plaintiffs' Response at 6).

These factually incorrect, improper legal and regulatory opinions should be excluded.

II. MR. QUICK'S REVIEW OF "EXAMPLES" OF CGMP ISSUES OVERSIMPLIFIES A COMPLEX CASE AND SKIRTS THE CORE CLASS CERTIFICATION ISSUE.

Mr. Quick's opinions must also be excluded because he did not conduct a proper factual investigation to support his conclusions. Plaintiffs do not dispute that Mr. Quick admitted to reviewing only certain "examples" or "exemplars" of the types of cGMP issues that would, in his opinion, impact all of the Defendants' VCDs equally over the entire time these products were being manufactured for sale in the United States. (*See, e.g.*, Quick Dep., Vol. I, 106:11, 112:14-24, 168:9-11, 177:20-24). Instead, Plaintiffs mischaracterize Defendants' argument as faulting Mr. Quick for failing to review "every single document in the case." (Plaintiffs' Response at 11.) That is not what Defendants have argued. Rather, Defendants explained that Mr. Quick seeks to offer sweeping legal conclusions that all Defendants' products were adulterated without any factual basis for such testimony.

This deficiency goes hand-in-hand with the impropriety of Mr. Quick's sweeping legal conclusions, themselves, discussed above. Because he felt no need to inquire about the impact of a given cGMP issue, any corrective action taken to address that issue, or whether the FDA found a manufacturer's response on a given issue satisfactory, he conducted nothing more than a cursory review of a few examples of cGMP issues present at each manufacturer. Based on this minimal information, he then concluded—contrary to any regulatory determination made by

the FDA—that every product manufactured at each of the Defendants' facilities during the entire relevant time period was "adulterated" under the FD&C Act by virtue of this handful of example cGMP issues. He reached this conclusion about the VCDs of all Manufacturer Defendants regardless of whether the FDA ever issued a warning letter or any other regulatory determination that a given manufacturer's product was adulterated. He also applied his opinion to all VCDs manufactured at the facilities at any time, with no analysis of when the individual issues he identified arose or how they would have affected actual VCD products. (*See* Section I, *supra*).

In order to reliably opine that all products were similarly affected by material cGMP violations in a manner and degree that would have caused the FDA to deem the valsartan product manufactured at a given facility adulterated, Mr. Quick would have had to undertake a substantial investigation into individual cGMP issues and the policies in place at those facilities. Rather than undertake this type of comprehensive and methodologically sound review, Mr. Quick took an unreliable short cut, relying on an incorrect legal assumption to hastily reach his class certification opinion that issues of adulteration/misbranding are common across all defendants and, therefore, across all purported class members. Importantly, the fact that Mr. Quick is being proffered as an expert at the class certification stage does not loosen the standard governing the reliability and admissibility of an expert's opinions. *See In re Blood Reagents Antitrust Litig.*, 783 F.3d at 187. Because

Mr. Quick failed to undertake anything close to the methodologically sound review necessary to arrive at his conclusions, his legal and regulatory opinions should be excluded for this reason as well.

CONCLUSION

For the foregoing reasons, and those set forth in Defendants' Motion, Defendants respectfully request that the Court exclude Mr. Quick's opinions in their entirety.

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Respectfully Submitted:

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CERTIFICATE OF SERVICE

I, Steven M. Harkins, an attorney, hereby certify that on June 16, 2022, I caused a copy of the foregoing document to be served on all counsel of record via CM/ECF.

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